K090323

SECTION 5: 510(k) SUMMARY

APR - 1 2009

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Katie Bray
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Date of preparation: February 6, 2009

Name of device:

Trade/Proprietary Name: Reprocessed Electrophysiology Catheters
Classification Name: Electrode recording catheter or electrode recording probe

Predicate Device	510(k) Title	Manufacturer
K072012	Reflexion Spiral™ Variable Radius Catheter	St. Jude Medical
K062251	Reflexion Spiral™ Variable Radius Catheter	St. Jude Medical

Device description:

Diagnostic Electrophysiology (EP) Catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a hand piece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tip of deflectable catheters can be deflected into a curve by manipulating the hand piece.

Indications for Use:

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures. In addition, the Lasso® 2515 Variable Circular Mapping Catheter and the Reflexion Spiral™ Variable Radius Catheter are designed for electrophysiological mapping of the atria of the heart.

Technological characteristics:

The design, materials, and intended use of Reprocessed Electrophysiology Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Electrophysiology Catheters is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent

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Healthcare Solutions' reprocessing of Electrophysiology Catheters includes removal of adherent visible soil and decontamination. Each individual Electrophysiology Catheter is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Electrophysiology Catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Electrophysiology Catheters perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Electrophysiology Catheters) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

Ascent Healthcare Solutions
c/o Ms. Katie Bray
Regulatory Affairs Manager,
10232 South 51st Street
Phoenix, AZ 85044

Re: K090323
Reprocessed Electrophysiology Catheters (See Enclosed List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: NLH
Dated: February 6, 2009
Received: February 9, 2009

Dear Ms. Bray:

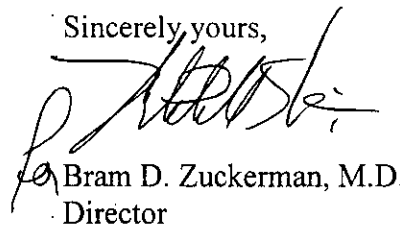
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Models Found SE:

Item No.	Description	Electrodes	French Size	Electrode Spacing	Lasso Diameter	Insertion Length	Curve Type
402800	Daig Reflexion™ Steerable EP Catheter	10	6Fr	2-5-2 mm	N/A	105 cm	Bi-Directional Med Curl
402804	Daig Reflexion Spiral™ Variable Radius EP Catheter	20	7Fr	1-4-1 mm	25-15 mm	99 cm	Bi-Directional 90°/180° Asymmetric
402865	Daig Reflexion Spiral™ Variable Radius EP Catheter	10	7Fr	6.30 mm	25-15 mm	99 cm	Bidirectional 180°
401661	Daig Reflexion™ Diagnostic EP Connecting Cable	N/A	N/A	N/A	N/A	150 cm	N/A

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090323

Device Name: Reprocessed Electrophysiology Catheters

Indications For Use:
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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram Zuckerman

(Division Sign-Off) 4/1/09
Division of Cardiovascular Devices

510(k) Number K090323